MCW Office of Research
Standard Operating Procedure

REQUIREMENTS & QUALIFICATIONS TO SERVE AS A PRINCIPAL INVESTIGATOR

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:
To define and explain the requirements and qualifications of persons who assume the role of Investigator of a human subject research project.

DEFINITIONS:
Human Subject: a living individual about whom an investigator (whether professional or student) conducting research obtains

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

Definition of Investigator
MCW IRB defines Principal Investigator (PI) of Human Subject Research as anyone who engages in the following:

1. any individual who leads or directs a research project involving human subjects
2. any individual who performs activities that engage MCW, Froedtert Health (FH) or Versiti in anyone else's research project
3. any individual that uses MCW, FH or Versiti resources; including lab equipment, physical space, or services
4. any individual who brings research data onto the campus
5. any individual who performs any research activity on MCW, FH or Versiti campus

A PI has overall responsibility for the conduct of a research project, including all technical, programmatic, financial, compliance, and administrative aspects. The PI is responsible for controlling the technical direction and academic quality of the project, and will ensure that the project is carried out in compliance with the terms, conditions, and policies of the institution and sponsor, when applicable.

Investigator (Office for Human Research Protections (OHRP)) - For the purposes of the HHS regulations, OHRP defines investigator as any individual who is involved in conducting human subject research studies.
Such involvement would include:

1. Obtaining information about living individuals by intervening or interacting with them for research purposes;
2. Obtaining identifiable private information about living individuals for research purposes;
3. Obtaining the voluntary informed consent of individuals to be subjects in research; and
4. Studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research projects are conducted by more than one investigator, and usually one investigator is designated the "principal investigator" (PI) with overall responsibilities for the project. In every human subject research project, investigators have certain responsibilities regarding the ethical treatment of human subjects. (45 CFR 46)

Investigator (Food and Drug Administration (FDA)) – The FDA defines investigator as an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team. (21 CFR 50.3 (d))

POLICY:

1. In accordance with *Corporate SOP: Principal Investigator Eligibility (RS.GN.160),* individuals who meet the eligibility requirements described may be identified as Principal Investigator on MCW human subject research projects.
    a. Residents and fellows may not serve as PI on projects. They may be co-Investigators collaborating with an eligible MCW PI.
    b. Individuals with the rank of Visiting Professor, Visiting Associate Professor and Visiting Assistant Professor are not eligible to serve in the PI role, nor are Volunteer (unpaid) Faculty, postdocs, or graduate students.
2. **Eligibility Requirements to be Principal Investigator for human subject research:**
    a. **Faculty –** Individuals with the faculty rank of Professor, Associate Professor, Assistant Professor and Instructor who are employeed by MCW Full-Time or with Full Professional Effort are eligible to serve as PI for human subject research projects.
        i. Individuals with the rank of Emeritus professor who were previously employeed by MCW with the faculty rank of Professor, Associate Professor, Assistant Professor and Instructor will remain eligible.
    b. **CTSI Consortium** - Individuals with the rank of MCW Adjunct Professor, MCW Associate Adjunct Professor, MCW Assistant Adjunct Professor, and MCW Adjunct Instructor who are employed by an institution in the CTSI consortium are eligible.
    c. **Froedtert Hospital (FH) Nurses** – Individuals who are employed by Froedtert Hospital as nurses who are not faculty at MCW, but whom FH has determined can provide value in conducting research. Individuals in this category must receive designation from the Froedtert Nursing Research Council, a PhD nurse researcher, and the Chief Nursing Officer.
    d. **Froedtert Hospital (FH) Pharmacists** - Individuals employed by Froedtert Hospital (FH) as pharmacists who are not faculty at MCW, but whom FH has determined can provide value in conducting research. Individuals in this category must receive designation from the Froedtert Pharmacy Research and Professional Development Committee.
    e. **Froedtert Menomonee Falls Hospital** - Individuals employed by Froedtert Menomonee Falls Hospital who are not MCW faculty, but for whom it has determined can provide value in conducting research.
        i. Individuals in this category must be a physician, hold a medical appointment at Froedtert Menomonee Falls Hospital, and receive designation from FH Corporate Compliance.
    f. **Froedtert West Bend Hospital** - Individuals employed by Froedtert West Bend Hospital who are not MCW faculty, but whom it has determined can provide value in conducting research.

i. Individuals in this category must be a physician, hold a medical appointment at Froedtert West Bend Hospital, and receive designation from FH Corporate Compliance.

g. **Versiti** - Individuals employed by Versiti, Inc. who are not MCW faculty, but for whom Versiti has determined can provide value in conducting research. Individuals in this category must be Versiti staff with a Masters degree or higher. Fellows may not be the PI on research projects. They may be co-Investigators collaborating with an eligible PI as identified per this policy .

h. **Children's Wisconsin** - Individuals employed by Children's Wisconsin (CW) who are not MCW faculty, but for whom CW has determined can provide value in conducting research. Individuals in this category must be CW staff with a Masters degree or higher. Individuals in this category must receive designation from CW Human Research Protection Program (HRPP).

3. Questions regarding eligibility to conduct research studies involving human subjects should be directed to the MCW HRPP Office.

Appointment review and approval process

When an individual with one of the above-listed non MCW faculty roles desires the PI role, a formal written request by the appropriate designated individual must be prepared setting forth the request and rationale.

The request should be made to the MCW HRPP and must include all of the following elements:

- Identification of the individual and their current position
- Identification of the qualifications of the individual
- Identification of the review of and support for the proposed research

For special exceptions regarding PI Eligibility on a protocol related to employment status, a request in writing should be submitted to the Director of the Human Research Protection Program.

Institutional Review Boards (IRBs)

1. MCW faculty work at a variety of inter-related but separate institutions. Many of these institutions have their own IRBs.
2. The MCW HRPP office recommends that Investigators contact the IRB for each institution that has jurisdiction before preparing an application as each IRB has its own application process and policies.
3. If the Investigator is aware of multiple institutions being involved with a project, they should contact the IRB to determine if multiple reviews can be avoided through the set up and execution of a reliance agreement as described in *IRB SOP: Reliance Agreements for Multi-Site Projects.*

Institutional Human Subject Research Educational Requirements

1. All Investigators engaged in the conduct of human subject research under the oversight of MCW IRB must complete the required human subjects research protections training prior to submission of a project for review and approval to the MCW IRB.
2. Investigators are required to remain up-to-date with required trainings to continue to conduct researchas outlined in the *IRB SOP: Human Subject Research Protections Training Requirements.*

REFERENCES:
45 CFR 46
21 CFR 50.3 (d)

SUPPORTING DOCUMENTS:
MCW Corporate SOP: Principal Investigator Eligibility (RS.GN.160)
IRB SOP: Reliance Agreements for Multi-Site Projects
IRB SOP: Human Subject Research Protections Training Requirments

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Effective Date:	07/01/2023
Version number:	7.0
Previous Version/date:	6.0; 06/15/2018
Responsible Office:	HRPP Office
Approval Date:	05/29/2023

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